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In the Supreme Court of the United States

OCTOBER TERM, 1979

ELI LILLY AND COMPANY, PETITIONER

v.

DOUGLAS M. COSTLE, ADMINISTRATOR,
ENVIRONMENTAL PROTECTION AGENCY

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIRST CIRCUIT

BRIEF FOR THE RESPONDENT IN OPPOSITION

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OPINIONS BELOW

The decision of the court of appeals (Pet. App. 1a-53a) is reported at 598 F. 2d 637. The decision of the Administrator of the Environmental Protection Agency is published at 43 Fed. Reg. 17776 (1978) (Pet. App. 59a-109a). The interim final regulations are published at 41 Fed. Reg. 48088 (1976).

JURISDICTION

The judgment of the court of appeals was entered on May 7, 1979 (Pet. App. 54a-58a). A petition for rehearing was denied on June 25, 1979. The petition for a writ of certiorari was filed on September 21, 1979. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

QUESTIONS PRESENTED

1. Whether Section 4 of the Administrative Procedure Act, 5 U.S.C. 553, requires EPA to provide an additional opportunity to comment on final regulations because those regulations differ to some extent from interim final regulations, as a result of changes made primarily in response to comments and data submitted during the comment period.

2. Whether the court of appeals applied the proper standard in reviewing the determinations of the Administrator.

STATEMENT

The Federal Water Pollution Control Act, 33 U.S.C. 1251 *et seq.*, establishes as a "national goal that the discharge of pollutants into the navigable waters be eliminated by 1985." 33 U.S.C. 1251(a)(1). To achieve that goal, polluters are required to limit discharges in accordance with "the best practicable control technology currently available" ("BPT") by July 1, 1977, and, by July 1983, in accordance with "the best available technology economically achievable ("BAT"). 33 U.S.C. 1311(b)(1)(A), (2)(A).

This case involves regulations that establish effluent limitations for the pesticide manufacturing industry in accordance with BPT. Development of these regulations began in 1976 with the distribution for comment of draft technical and support documents to interested parties, including petitioner. 41 Fed. Reg. 48088, 48093 (1976). On November 1, 1976, EPA published regulations in interim final form[1] and responded in detail to the

[1]This procedure was followed because of an order requiring the agency to adopt regulations effective immediately upon publication. *Natural Resources Defense Council* v. *Train*, 6 E.R.C. 1033 (D. D.C. 1973).

comments submitted on these materials. 41 Fed. Reg. 48088, 48093-48096 (1976). These comments had identified subcategorization of the industry, treatability of pesticides, and the need for more industry data as important issues. *Id.* at 48093-48094. Two volumes of materials explaining the derivation of the regulations were made available, and EPA specifically requested additional comments and data. *Id.* at 48088.

The interim regulations divided the pesticides industry into five subcategories: three governing organic pesticide manufacture (organo-nitrogen, organo-phosphorus, and halogenated organic pesticides) and one subcategory each for metallo-organic pesticide manufacture and pesticide formulation and packaging. *Id.* at 48089-48091. Effluent limits for specific pollutants were established based on the application of technologies for pesticide removal that included hydrolysis or carbon sorption. *Id.* at 48094. In developing these interim limitations, EPA utilized all the information that it was able to generate and collect. *Id.* at 48089. Data from seven plants were used in deriving the interim regulations (Pet. App. 13a).

The agency received extensive comments on the interim regulations, particularly regarding the subcategorization of organic pesticides (Pet. App. 87a-89a). The comments urged, *inter alia*, that the agency consider the extent to which pesticides are subject to treatment in developing a subcategorization plan, suggesting that the record did not support the significantly different limits assigned to the three proposed organic manufacturing subcategories (Pet. App. 87a-89a). Generally, the industry urged the creation of more subcategories (Pet. App. 9a, 89a). In response to these comments, the agency thoroughly reexamined its data base, expanded its literature review, and inspected all plants treating

pesticides with the recommended carbon sorption and hydrolysis systems, including two facilities that had not supplied data for the interim regulations (see Pet. App. 15a-16a).

Additional data were collected from pesticides manufacturers, including petitioner.[2] Petitioner employs a carbon treatment system for wastewater from its process for the manufacture of trifluralin, an organo-nitrogen pesticide. That process was analyzed both by EPA's contractor, ESE, and by petitioner. The trifluralin effluent data obtained by ESE were made available to petitioner (Pet. 21 n.9). Petitioner discovered significant differences between its own and ESE's analysis of presumably identical samples taken from the plant (Pet. 20-21 n.9). Petitioner informed the agency that ESE's figures were substantially higher than its own (demonstrating less effective treatment), but the discrepancy was not explained (Pet. App. 24a-25a). In developing the final rule, the agency used the higher ESE effluent values for petitioner's plant, thereby making the final discharge limitations less stringent than if petitioner's figures had been used (*ibid.*).

The final regulations were promulgated on April 25, 1978 (Pet. App. 59a-109a). Some changes from the interim regulations were made, primarily as a result of industry comments (Pet. App. 6a). With regard to subcategorization, the agency found, as many commenters had urged, that there should not be three different organic pesticide subcategories and that all organic pesticide manufacturing plants could treat their

[2]Industry provided 95% of the data used in calculating the final limitations (Pet. App. 16a).

pesticides to achieve the same effluent level (Pet. App. 64a). Accordingly, the three subcategories were consolidated into one organic pesticide category (Pet. App. 63a-64a).

Overall, the final limitations were more stringent than the interim ones for some producers and less stringent for others (Pet. App. 5a). For petitioner's trifluralin plant, the final limitations are lower than the interim ones, but, as petitioner notes (Pet. 21 n.9), they are higher than petitioner's actual discharge as observed either by ESE or petitioner. After the final regulations were issued, one company petitioned the agency for reconsideration alleging, *inter alia*, that analytical techniques were unavailable to detect many pesticides at the levels set. On reconsideration of the record, the agency limited the applicability of the final regulations to 49 of several hundred pesticides (Pet. App. 5a).

Eleven pesticide manufacturers, including petitioner, brought suit to challenge the regulations. The court of appeals held that petitioner had a fair opportunity to present its views on the issues involved in the organic pesticide rulemaking (Pet. App. 6a-16a). Regarding subcategorization, the court found that the consolidation of the subcategories was suggested by, and in part a logical outgrowth of, industry's comments (Pet. App. 9a, 34a-35a). Similarly, the court found that a fair opportunity to comment on the issue of pesticide treatability had been presented (Pet. App. 11a-12a).

With respect to the data base supporting the final regulations, the court noted that 82% of the data was from the seven facilities that had formed the basis for the interim regulations and that all relevant information concerning those facilities had been disclosed and subject to comment (Pet. App. 13a-14a). The court also found

that the treatment technologies at the two additional facilities considered in the final regulation conformed to EPA's "fully disclosed model technology" and were similar to those used at the other plants (Pet. App. 15a). Finally, the use of the additional data from those two plants rendered the final limitations less stringent (Pet. App. 15a-16a). In sum, the court of appeals concluded that the industry was provided with an adequate opportunity to comment on the regulations (Pet. App. 11a-12a).

The court of appeals remanded the case to EPA for the limited purposes of reconsidering discharge data from Olin Corporation's McIntosh, Alabama plant (Pet. App. 33a), and reconsidering the costs of meeting the metallo-organic pesticide limitation (Pet. App. 40-43a). The court retained jurisdiction of the case pending the action of the agency on remand (Pet. App. 52a-53a).

ARGUMENT

The decision of the court of appeals is correct and is not in conflict with any other court of appeals decision. Further review of this essentially fact bound case is unwarranted.

1. Petitioner contends (Pet. 10-13, 16-21) that it should be provided an opportunity to comment on the final pesticide limitations issued by EPA because the final rules differ from the interim final rules. It is well-established, however, that final regulations may differ from those proposed without triggering the need for a new comment period. See *American Frozen Food Institute* v. *Train*, 539 F. 2d 107, 134 (D.C. Cir. 1976); *International Harvester Co.* v. *Ruckelshaus*, 478 F. 2d 615, 632 (D.C. Cir. 1973); *American Iron and Steel Institute* v. *EPA*, 568 F. 2d 284, 293 (3d Cir. 1977);

South Terminal Corp. v. *EPA*, 504 F. 2d 646, 658-659 (1st Cir. 1974); *California Citizens Band Ass'n* v. *United States*, 375 F. 2d 43, 47-49 (9th Cir.), cert. denied, 389 U.S. 844 (1967). Petitioner nevertheless asserts that, in the particular circumstances of this case, it was deprived of an opportunity to comment.

The suggestion (Pet. 11-12, 20) is that because the agency relied partly on data submitted during the comment period, petitioner was deprived of an opportunity to comment.[3] After a thorough examination of the record, the court of appeals correctly found that none of the new data submitted raised any new issues for comment (Pet. App. 12a-16a). Seven of the nine plants used for collecting data were listed in the interim development document and 82% of the data points were derived from these plants (Pet. App. 12a-13a). Moreover, EPA's methodology was revealed to petitioner prior to the comment period and that methodology did not change (Pet. App. 14a; compare Pet. App. 69a-70a with 41 Fed. Reg. 48088, 48091 (1976)). The fact that the companies did not know during the comment period what the ultimate numbers would be did not restrict their ability to comment on the method used to collect data or how the data were used.

The principal change in the regulations that petitioner seeks to comment upon is the consolidation of the three interim organic pesticide subcategories that resulted in a lower effluent limitation for trifluralin (Pet. 19-21). Clearly, petitioner had an opportunity to comment on

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[3]Ironically, petitioner and the other ten petitioners below attacked the regulations substantively on the ground that EPA did not collect sufficient data (Pet. App. 12a n.11). In fact, the court of appeals found (Pet. App. 29a) that data difficulties in this area exist partly because "the industry is very reticent about revealing what it does (or could) know."

this issue. The agency's method of subcategorization was one of the industry's principal concerns with the draft and interim regulations. It was certainly foreseeable that the final subcategories would be different from the interim ones because the industry was "almost unanimous in condemning the three original subcategories" (Pet. App. 9a). One commenter presented a statistical analysis indicating that the three organic pesticide subcategories were indistinguishable from each other (*ibid.*). One repeated comment was the request that the three subcategories be treated more equitably (Pet. App. 10a). Thus, the actual result of a consolidation of the subcategories was a logical response to industry comments.

Petitioner contends (Pet. 19-21) that it has been particularly deprived of an opportunity to comment, as compared to the other 10 plaintiffs in the court of appeals, because it had no objection to the trifluralin limitations that were established in the interim regulations. This contention is without merit. Petitioner was aware that the limitations might be changed in the final regulations in response to comments. Petitioner had every opportunity to comment on what it thought to be a proper effluent limitation for trifluralin. There is no requirement that a party be dissatisfied with the numbers set forth in interim or proposed regulations in order to be eligible to comment on those regulations.[4] Moreover,

[4]Petitioner's suggestion (Pet. 19) that the court of appeals did not consider its individual contentions is without foundation. The court found that any divergence of EPA's data from petitioner's redounded to petitioner's benefit (Pet. App. 24a-25a, 31a) and that the claim that petitioner generated an untreated waste stream was "unconvincing" (Pet. App. 31a). Finally, as petitioner concedes (Pet. 19 & n.7), the court specifically stated that "[r]egulatory targets have no guarantee that proposed effluent limits, which they are capable of meeting, will stay the same. * * *[T]hose interest groups preferring looser limits are not the only ones whose comments are solicited."

petitioner does not suggest how it has been disadvantaged by its alleged inability to comment. EPA's use of ESE's higher figures resulted in a higher allowable discharge, to the benefit of petitioner (Pet. App. 25a). And, in any event, petitioner itself states that the discharge measured at its plant is within the effluent limitations set forth in the final regulations (Pet. 21 n.9). In sum, petitioner had ample notice and opportunity to comment in this rulemaking proceeding. It simply chose not to participate.

Finally, petitioner's assertion (Pet. 13-16) that this case conflicts with decisions of other courts of appeals is erroneous. The cases cited by petitioner (Pet. 13-16, 24-27) are quite different from this case because they involve unexplained, unsupported, or erroneous agency data or methodology, or the withholding of all data from the industry. In *National Crushed Stone Ass'n* v. *EPA*, 601 F. 2d 111, 117-119 (4th Cir. 1979),[5] the court found that the agency did not explain the reasoning involved in reaching its final figures and that the validity of the data relied upon was open to serious doubt. Here, the court found that the petitioners below did not establish that the data relied upon were open to serious question (Pet. App. 22a-26a). In *Weyerhaeuser Co.* v. *Costle*, 590 F. 2d 1011 (D.C. Cir. 1978), the court found that the agency's explanation of its methodology was inadequate, and the agency admitted that some of its computations were erroneous. 590 F. 2d at 1029-1030. In *United States* v. *Nova Scotia Food Products Corp.*, 568 F. 2d 240 (2d Cir. 1977), the Food and Drug Administration had concealed all of the research on which its rules were

[5]The government has filed a petition for a writ of certiorari, No. 79-770 (Nov. 15, 1979), to review the decision of the court of appeals in this case on an unrelated issue.

based, and the court specifically noted that it was not dealing with a case where the research data were supplied by the interested parties themselves. In *Portland Cement Ass'n* v. *Ruckelshaus*, 486 F. 2d 375 (D.C. Cir. 1973), cert. denied, 417 U.S. 921 (1974), the court remanded an emission standard because neither the test methodology nor the underlying data had been made available for comment. 486 F. 2d at 392-393.

2. Petitioner also contends that the court of appeals incorrectly engaged in de novo review (Pet. 22-24), substituted its own judgment for that of the agency (Pet. 26-27), and granted undue deference to the agency (Pet. 22-25). These contentions are without merit. Petitioners below challenged the procedures used by ESE in collecting data. EPA clearly concluded that the data were reliable (Pet. App. 22a), but the court of appeals went on to make its own review of the procedures. It considered the criticism in detail (see Pet. App. 23a-24a n.24), allowing three rounds of briefing memoranda (Pet. App. 16a), but found that the record evidenced "concern for careful procedure" (Pet. App. 23a) and that, although petitioners below had "combed the record" searching for laboratory errors (Pet. App. 22a), they had not established that EPA erred in relying on ESE data (Pet. App. 22a-26a). The court's careful and thorough review comports fully with the standards established in *Citizens To Preserve Overton Park* v. *Volpe*, 401 U.S. 402 (1971).

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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